REMARKS

Claims 1-21 are pending in the present application.

I. The Restriction Requirement and Applicant's Provisional Election

The Examiner required restriction, under 35 U.S.C. §§ 121, 372, between Groups 1 to 6 as these inventions or groups of inventions allegedly are not so linked as to form a single general inventive concept under PCT Rule 13.1. Office action, pages 2-3. The Examiner further required restriction to one polypeptide sequence. Office action, page 3.

In response, Applicants hereby provisionally elect, with traverse, Group 2, claims 3-6, 9-14 and 21, drawn to polynucleotides encoding the polypeptides of Group 1; polynucleotides having at least 70 % sequence identity to the polynucleotides encoding the polypeptides of Group 1; polynucleotides which hybridize to the polynucleotides encoding the polypeptides of Group 1; complementary sequences of the polynucleotides encoding the polypeptides of Group 1; polynucleotides comprising SEQ ID NO: 8-14 and fragments thereof; polynucleotides having at least 70 % sequence identity to the polynucleotides comprising SEQ ID NO: 8-14, fragments, complementary sequences, expression vectors and host cells therof; and methods of recombinant expression of a host cell.

Applicants further provisionally elect, with traverse, the polypeptide depicted in SEQ ID NO: 6 and the polynucleotide encoding the elected polypeptide, SEQ ID NO: 13.

Applicants note that the non-elected method claims should be rejoined, as a matter of right, upon allowance of a product claim. *See* MPEP § 821.04.

II. The Polypeptides Of Group 1 And The Polynucleotides Of Group 2 Exhibit Corresponding Special Technical Features

Applicants traverse the restriction requirement because the unity of invention standard must be applied in national stage applications. Section 1850 of the Manual of Patent Examining Procedure (original 8th edition, published August, 2001) (hereinafter "MPEP") provides that

> when the Office considers international applications . . . during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when considering unity of invention of claims of different categories without regard to the practice in national applications filed under 35 U.S.C. 111 . . . .
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> . . .
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> In applying PCT Rule 13.2 to . . . national stage applications under 35 U.S.C. 371, examiners should consider for unity of invention all the claims to different categories of invention in the application and permit retention in the same application for searching and/or preliminary examination, claims to the categories which meet the requirements of PCT Rule 13.2 . . . .

MPEP at page 1800-60 to -61.

MPEP section 1893.03(d) reiterates the Examiner's obligation to apply the Unity of Invention standard PCT Rule 13.2 instead of U.S. restriction/election of species practice:

> Examiners are reminded that unity of invention (not restriction) practice is applicable . . . in national stage (filed under 35 U.S.C. 371) applications.

Id. at page 1800-149, col. 1.

Indeed, according to Example 17, Part 2 of Annex B to the PCT Administrative Instructions, the Examiner is obliged to find that "the protein and the DNA sequence exhibit corresponding special technical features" and that, therefore, there is no lack of unity between claims directed to a protein "X" and the DNA sequence that encodes protein "X."

Thus, in the present case, unity of invention does exist at least as between claims 1-2 and 15 of Group 1, as drawn to the polypeptides of SEQ ID NO: 6, and claims 3-6, 9-14 and 21 of Group 2, drawn, in part, to the polynucleotides which encode those polypeptides. Therefore, Applicants respectfully request that the Examiner withdraw the Restriction Requirement at least as to claims 1-6, 9-15 and 21 of Groups 1 and 2, and examine those claims in a single application.

III. In Accordance With Office Practice, The Examination Of Claims To Ten Polynucleotide Sequences Does Not Create An Undue Burden

Applicants draw the Examiner's attention to Section 803.04 of the Manual of Patent Examining Procedure. While contending that nucleotide sequences that encode different proteins "constitute independent and distinct inventions" the Commissioner has decided to "permit a reasonable number of such nucleotide sequences to be claimed in a single application" so as to "further aid the biotechnology industry in protecting its intellectual property." See id. To this end, the Patent Office "determined that normally ten sequences constitute a reasonable number for examination purposes" and that that number does not create "an undue burden on the Office." Id. Indeed, the Office states that "up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction." Id. Accordingly, the Examiner's contention that SEQ ID NO: 8-14 are "distinct from the other" and, therefore, subject to restriction, is not consistent with Office practice.

Indeed, under the "Examples of Nucleotide Sequence Claims" subsection of Section 803.04, the Office states that "[O]nly the *ten* nucleotide sequence selected in response to the restriction requirement and any other claimed sequences which are patentably indistinct therefrom *will* be examined" (emphasis added).

For this reason, Applicants further traverse the restriction requirement. Applicants contend that the polynucleotides of SEQ IN NO: 14-17 in Group 2 (claims 3-6, 9-14 and 21), drawn to the polynucleotides encoding the polypeptides of SEQ ID NO: 7-10, should be examined alongside the elected polynucleotides of SEQ ID NO: 13. Accordingly, Applicants kindly request that the Examiner rejoin SEQ ID NO: 6-10 and examine together these five polynucleotides.

IV. The Search Of Groups 1 and 2 Is Not Unduly Burdensome

Applicants also traverse the restriction requirement on the grounds that the search and examination of at least Groups 1 and 2 is not unduly burdensome. According to MPEP section 803 "if a search and examination of an entire application can be made without serious

burden, the Examiner must examine it on the merits, even though it includes claims to independent and distinct inventions." As the polynucleotides of Group 2 encode the polypeptides of Groups 1, Applicants suggest examination of at least Groups 1 and 2 can be made without serious burden.

In particular, as Applicants have elected the polynucleotides of SEQ ID NO: 13 of Group 2, it is respectfully requested that claims 1-2 and 15 of Group 1, as drawn to the polypeptides of SEQ ID NO: 6, be rejoined with the elected invention.

V. Conclusion

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

If there are any fees due in connection with the filing of this response, please charge the fees to Deposit Account No. 19-0741. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should be charged to our Deposit Account.

Respectfully submitted,

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